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| APPLICATION NO.                             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/078,042                                  | 02/19/2002  | Donald C. Roe        | 8430                | 4980             |
| 27752                                       | 7590        | 05/21/2007           | EXAMINER            |                  |
| THE PROCTER & GAMBLE COMPANY                |             |                      | KOPPIKAR, VIVEK D   |                  |
| INTELLECTUAL PROPERTY DIVISION - WEST BLDG. |             |                      | ART UNIT            | PAPER NUMBER     |
| WINTON HILL BUSINESS CENTER - BOX 412       |             |                      | 3626                |                  |
| 6250 CENTER HILL AVENUE                     |             |                      |                     |                  |
| CINCINNATI, OH 45224                        |             |                      |                     |                  |
| MAIL DATE                                   |             | DELIVERY MODE        |                     |                  |
| 05/21/2007                                  |             | PAPER                |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/078,042             | ROE ET AL.          |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Vivek D. Koppikar      | 3626                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 3/28/07.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-10 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Application*

1. Claims 1-10 have been examined in this application. This communication is the first action on the merits since the applicants filed a Request for Continued Examination (RCE) on March 28, 2007.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2 and 5-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of US Patent Number 6,055,506 to Frasca, Jr.

A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

- a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);
- d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Col. 4, Ln. 54-67).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

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c) at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca, Jr.: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(B) As per claim 2, in the system of Sheehan in view of Frasca, Jr. the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

(C) As per claim 5, in the system of Sheehan in view of Frasca, Jr. the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 6, Sheehan in view of Frasca, Jr. teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

- a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);

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d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67);

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating information pertaining to the health of an individual (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(E) As per claim 7, in the system of Sheehan in view of Frasca, Jr. at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32)

(F) As per claim 8, the system of Sheehan in view of Frasca, Jr. includes:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);  
b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);  
d) an information presentation mechanism displaying the information pertaining to the health of an individual, wherein the at least one information presentation mechanism is selected from the group: a graphical summary screen, an icon based summary screen, a help guide, an

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anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(G) As per claim 9, Sheehan in view of Frasca, Jr. teach a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

a) selecting at least one health parameter appropriate for the particular individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);  
b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);  
c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46); and  
c) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

d) analyzing the data via at least one data analysis mechanism to define an out-of-control situation requiring intervention and/or potential causes or remedies of the out-of-control situation wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(H) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr., as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Ekblad with the

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motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr., as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.

(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

***Response to Arguments***

6. Applicant's arguments filed on March 28, 2007 have been fully considered but they are not persuasive. The applicant's arguments will be addressed in the same order as they were addressed in the "Remarks" filed on March 28, 2007.

(1) Applicants arguments with regard to the Williamson reference are moot in view of the new ground of rejection in which the Williamson reference is no longer used.

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(2) Applicants argue that Sheehan does not teach or suggest a population comparison. This argument is moot in view of the new grounds of rejection over the Frasca, Jr. reference which teaches a population comparison.

(3) Applicants argue, with regards to Claim 7, that Sheehan does not teach a data acquisition device that includes a PDA (i.e. portable device). However, as pointed out in the rejection above, Sheehan does in fact teach the use of a portable device (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32).

(4) Applicants argue, with regards to Claim 8, that Sheehan does not teach a data acquisition mechanism transferring data relevant to a particular health condition from a data measurement mechanism to a storage medium. However, the combined teachings of Sheehan in view of Frasca, Jr. do in fact teach these very features.

(5) Applicants arguments with regards to Claims 3 and 9 are moot in view of the new grounds of rejection over the Frasca, Jr. reference.

(6) With regards to Claim 4, in response to applicant's argument that Loman is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Loman is directed to the problem failure analysis of a system and Claim 4 of the instant invention is also directed at this same problem, therefore the examiner takes the position that Loman is reasonably pertinent to the particular problem of reliability engineering with which the instant invention is concerned with.

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***Conclusion***

7. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

5/11/2007

*Carolyne Block  
Patent Examiner-3626  
5/11/07*